

K964818 ORION SERIES SURGICAL LASER SYSTEM (Q-SWITCHED ND:YAG CONFIGURATION)

Jun 17, 1997
200 days to decision

K964818 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k964818/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 29, 1996
Decision date	Jun 17, 1997
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Laserscope
Location	Santa Clara, CA, US
Contact	LISA MCGRATH
510(k) history	60 submissions · 60 cleared · 1985-2006

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k964818/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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